UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,598	09/23/2005	Thomas J. Guttuso Jr	176/61332	7385

7590 05/16/2007

Edwin V Merkel
Nixon Peabody
Clinton Square
PO Box 31051
Rochester, NY 14603

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,598	GUTTUSO JR, THOMAS J.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 47-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *49, and 51-56* is/are allowed.

6)☒ Claim(s) *1, 3, 5 -6, 14 -19 and 47-48* is/are rejected.

7)☒ Claim(s) *2,4,7-13 and 50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The response filed **2//5/07** presents remarks and arguments to the office action mailed **8/03/06**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

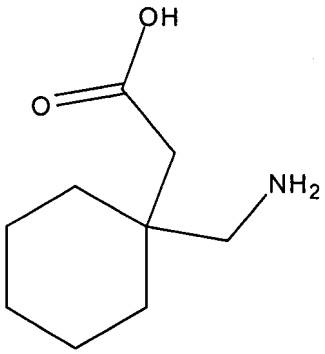
Information Disclosure Statement

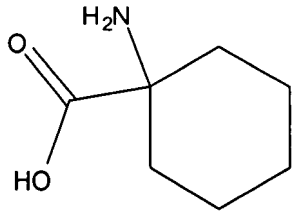
The information disclosure statement (IDS) submitted on February 05, 2007 has been received and acknowledged.

Allowable Subject Matter

Claims 2, 4,7-13 and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 49, and 51-56 are allowed. The patent 6,310,098 is cited to show the state of the art using 1-aminocyclohexane carboxylic acid. The reference teaches analogs of gabapentin for the treatment of hot flashes. The compounds





gabapentin is a homolog of L-aminocyclohexane carboxylic acid. The set compound is devoid of the substituent in the heterocyclic group that is required of claims 47-56. Thus the prior art does not anticipates nor suggest instant claims 47-56.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Plaitakis US 5,028,622.

Plaitakis teaches the instant claim 1 a method of treating a neurodegenerative disease administering L-isoleucine (see col. 1, lines 15-18), wherein the compound is L-isoleucine, L-leucine (see col. 1, lines 17-18) as in claims 3 and 6 administered in an amount of 5000 mg per day (see col5, line 35) as in the amount of 0.3-30 g. After

calculation, 5000 mg is equal to 5.0 g as in claim 14, which is within the range administered by the reference. The reference also teaches administering the composition orally (see col. 5, line 46) as in claim 15, note the pharmaceutical composition (see col. 12, line 39) and in a pharmaceutically acceptable carrier. Thus the recited claims are anticipated by the reference. Note pharmaceutical composition as in claim 16, wherein the composition is in a liquid or solid form as in claims 17 and 19 are also anticipated-thus the reference teaches (see col. 6, lines 5-12), wherein the composition is a given orally in a powdered form. Hence the above claims meet the anticipation limitation.

Claims 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Meakins et al. J. Nutrition128;720-727.

The reference teaches administering L- methionine to women (see abstract). Note that hot flash, migraine, irritable bowel syndrome etc., – does not alter the compound nor the composition. The reference discloses L-methionine (see, e.g., the abstract). Consequently, the reference anticipates the claimed invention defined in claim 47.

Claims 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Vitaminworld.com

Vitamin world sells L-methioninine as single unit in tablet forms does not alter the compound nor the composition. The reference discloses L-methionine (see, enclosed). Consequently, the reference anticipates the claimed invention defined in claim 47.

Claims 47-48 is rejected under 35 U.S.C. 102(b) as being anticipated by www.dellis.com/pages/supp/catalog/bottom.

The above reference teaches a 60 packet of 6 tablets contains more than one amino-acid composition such as methionine, norleucine and isoleucine in their L-forms (see page 7). The reference discloses methionine, norleucine and isoleucine in their L-forms (see, enclosed). Consequently, the reference anticipates the claimed invention defined in claim 48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-6, 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plaitakis US 5,028,622 taken with Herbert, US 2003/0144244 A1 which has priority of 01/30/02 (-60/353,717 which is earlier than the filing date of the instant application in view of Richardson US 6,200,758 B1.

Plaitakis teaches the instant claim 1 a method of treating a neurodegenerative disease administering L-isoleucine (see col. 1, lines 15-18), wherein the compound is L-

isoleucine, L-leucine (see col. 1, lines 17-18) as in claims 3 and 6 administered in an amount of 5000 mg per day (see col5, line 35) as in the amount of 0.3-30 g. After calculation, 5000 mg is equal to 5.0 g as in claim 14, which is within the range administered by the reference. The reference also teaches administering the composition orally (see col. 5, line 46) as in claim 15, wherein the compound is in a pharmaceutical composition (see col. 12, line 39). Note pharmaceutically acceptable carriers as in the instant claim 16, note liquid or solid composition form is taught (see col. 6, lines 5-12), wherein the composition is a given orally in a powdered form as a BCAA (branched chain amino acid) powder. It is the Examiners position that liquid or solid forms (as in claims 17 and 19) are obvious variants since a drug can be administered in an encapsulated powdered form which is considered solid, or when mixed with a liquid – a liquid form.

Herbert teaches a method of treating obsessive compulsive disorder, attention deficit disorder, neurodegenerative disorders such as alzheimer's, migraines (see page 2, para. 0011) by administering a composition of S-adenosyl-L-methionine (SAMe) compound. SAMe is a metabolite of L-methionine, thus administering SAMe when in the system metabolizes to methionine is administering the compound as claimed. Also methionine is a branched amino acid.

Richardson teaches administering a BCAA drink to patients for the treatment of tardive dyskinesia (a neurological disorder)(see col. 9, lines 23-31) wherein the BCAA formulation is a medical food formulation as in claim 18 containing valine isoleucine (see col. 12, lines 36-44).

One of ordinary skill in the art would have been motivated to combine the above cited references for the treatment of a neurodegenerative disorder because BCAA have been used to treat neurological disorder. The combined references use branched amino acid for the treatment of a neurodegenerative disorder. Therefore one of ordinary skill in the art would be motivated to make and used a drug/nutritional formulation with the claimed amino acids for the treatment of a neurodegenerative disease and expect to be successful. For example deficiency from methioninine leads to dementia, deficiency in leucine leads to fatigue, headaches, deficiency in isoleucine leads to mental and physical disorders-thus one of ordinary skill will be motivated to administer these essential amino acid to patients with these disorders and expect to be successful. The motivation comes from the combined references where BCAA have been used in the treatment of neurodegenerative disorders. Moreover, the motivation as to why one of ordinary skill would conceive and use similar compounds was rendered by the Court which stated in *In re Gyurik et al.,* 596 F.2d 1012, 201 USPQ 552 at 557. "In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the prima facie case of obviousness rises from the expectation that compounds similar in structure will have similar properties". Thus, the instantly claimed method using the compounds would have been suggested to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
4/17/07

Ardin H Marschel 5/14/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER